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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,983	08/31/2001	Lieven Stuyver	11362.0008.DVUS02	2800

7590 04/10/2003

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HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
1637	13

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/943,983	STUYVER ET AL.
	Examiner	Art Unit
	Kenneth R Horlick	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15-42 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 15-42 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 08/31/01 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 08/913,833.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1. (<u>2</u> pages) | 6) <input type="checkbox"/> Other: _____ |

1. Claims 16 and 20 are objected to as being duplicates of claims 15 and 19, respectively. Although the preambles are different, the claims are drawn to kits which are examined based only on the kit components, which appear to be identical in the respective claim sets. The different language in the preambles relates only to "intended use" of the kits, which is not given patentable weight.

2. Claims 17 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are confusing because "the primer" lacks proper antecedent basis in claims 15, 16, and 38, which refer to a "set of primers". Correction is required.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mellors et al. (1995) or Shafer et al. in view of WO 94/12670.

These claims are drawn to kits comprising at least two reverse transcriptase gene probes, wherein each probe is capable of hybridizing specifically to one or more target codons within any region I to VIII as represented in Fig. 1, said probes optionally fixed to a solid support.

Mellors et al. teach numerous HIV-1 reverse transcriptase mutations associated with drug resistance (see especially pages 8 and 9). Specifically, this reference teaches mutations at codons: 41 (instant region I); 50 (instant region II); 65, 67, 69, and 70 (instant region III); 74 and 75 (instant region IV); 181 and 184 (instant region VI); 215 (instant region VII); and 219 (instant region VIII).

Shafer et al. teach numerous HIV-1 reverse transcriptase mutations associated with drug resistance (see especially abstract and Table 1 on page 74). Specifically, this reference teaches a mutation at codon 151 (instant region V).

Neither of these references teaches a kit comprising at least two probes immobilized to a solid support such that said probes may simultaneously hybridize to their respective target sequences.

WO 94/12670 discloses an assay format wherein multiple different polynucleotide probes are immobilized to a solid support, and simultaneously hybridized with all corresponding target sequences which may be present in a sample of interest (see especially pages 23 and 35-44).

One of ordinary skill in the art would have been motivated to apply multiple probes for detecting the various mutations of Mellors et al. or Shafer et al. in the assay format of WO 94/12670 because this would have conveniently identified all known, drug-resistance-associated reverse transcriptase mutations present in a given HIV1-containing sample. The skilled artisan would have been motivated to make the claimed kits for use in such a method, as it was well known and common knowledge in the art to package together reagents into a kit for the convenience of practicing methods requiring such reagents. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

4. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mellors et al. (1995) or Shafer et al. in view of WO 94/12670, and further in view of Tedder et al. (WO 93/21339).

This claim is drawn to the kit of claim 15 or 16 as described and rejected above, further comprising a primer which is any one of SEQ ID NO: 39, 162, 163, or 164.

None of the references cited in paragraph 3 above teaches a primer having one of these sequences.

Tedder et al. disclose a primer useful in analyzing samples for point mutations in the reverse transcriptase gene of HIV-1. This primer (Primer SPP6) is nearly identical to instant SEQ ID NO:164, differing merely in that it has 3 additional nucleotides at the 5'-end (see bottom-half of page 26).

One of ordinary skill in the art would have been motivated to add the primer of instant SEQ ID NO:164 to a kit as suggested by the combination of Mellors et al. or Shafer et al. and WO 94/12670, because Tedder et al. disclosed a primer nearly identical to said SEQ ID NO:164 as being advantageous in analyzing HIV-1 reverse transcriptase gene mutations. The skilled artisan would have surely understood from Tedder et al. that trivial variations of Primer SPP6, including for example adding one, two, or three nucleotides to the 5'-end, would be expected to have the same specificity and properties, and function in the same manner. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kit.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,331,389, as well as over claims 1-9 of U.S. Patent No. 6,087,093. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the claimed kits contain the patented probes, and said probes are used in the patented methods and compositions. Thus, the patented probes, compositions, and methods would have been clearly suggestive of the instantly-claimed kits.

6. Claims 18-42 are free of the prior art, but are rejected for other reasons. No claims are allowable. No prior art has been found teaching or suggesting kits comprising the required SEQ ID NO:s.

7. Uhlen et al. (US 5,534,424) is made of record as a reference of interest, as it discloses a region of the HIV-1 reverse transcriptase gene which comprises instant SEQ ID NO:164, with an additional eight nucleotides (Uhlen et al. SEQ ID NO:3 in column 13).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kenneth R. Horlick, Ph.D.
Kenneth R Horlick
Primary Examiner
Art Unit 1637

April 2, 2003